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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,789	01/27/2004	Michael J. Cusick	OSTEONICS 3.0-449	4013
530	7590	11/30/2005	EXAMINER	
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			AMARELD JR, ROBERT W	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/766,789	CUSICK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Robert W. Amareld, Jr.	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 January 2004.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-51 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-51 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 27 January 2004 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/23/04, 6/14/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____ .                                  |

## DETAILED ACTION

### *Drawings*

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "worm" (132) & "teeth" (144) must be represented more clearly or the feature(s) canceled from the claim(s). The structure of the "worm" is unclear from the specification and drawings. A drawing of the worm interaction with the device and it's teeth should be provided, however no new matter should be entered that is not supported by the description within the specification.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: The description of the drawings for Figures 5 and 6 reference lines 5-5 and 6-6 respectively. The drawings of Figure 3 show two dotted lines, one that is labeled 5.6-5.6 at each end and one that is not labeled. If 5.6-5.6 is meant to represent the two lines of 5-5, and 6-6 then it should be clarified and only one number should be used to describe the line.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance. **The applicant is cautioned to avoid new matter not supported in the specification with in amended drawings.**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

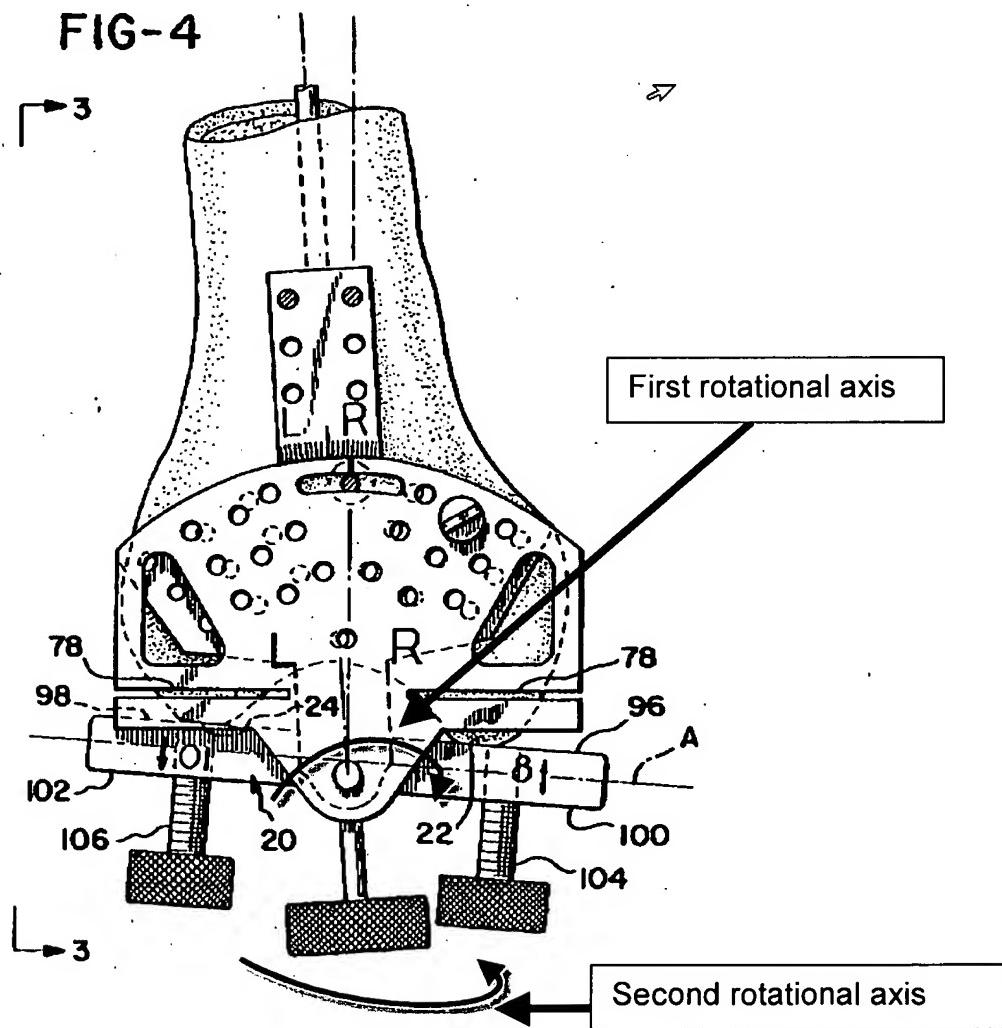
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 11-18, 23-30, 35-45, 48-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Pohl (US Pat# 4703751). Pohl discloses an apparatus (10) comprising a guide plate (18) and alignment means along a translational path of the rod 14 and/or bolt (62) along the axis of the shaft (34), the device having two rotational paths shown in the figure following this paragraph, being around the boss (44) and the rod (14). The bolt (62) is threaded into the shaft (34) and allows for controlled translation relative to the guide, being a first assembly. The second assembly (14) allows for

rotation about a first rotational path in controlled increments by turning the knob (32) in relation to the rod (14) and the device (10). The third assembly of the fan shaped portion (40) with the cutting plate(18) and the shaft (34) and boss( 44) allow for controlled rotation about a second rotational axis in controlled increments affected by gear/bolt (86, 88), additionally, the boss being a releasably coupling agent of the guide. The assembly of the cutting plate (18) is considered the housing as it houses the fan portion (40), which is a rotatable plate. The first assembly of the bolt (62) also comprises the yoke, which consists of the two spaced apart bars (104,106) which are transversely threaded rods for slidably coupling the yoke cross-member bar (20), where rotation of bolt (62), a threaded rod, allows for translation of the yoke relative the rest of the assemblies, where when the bolt 62 is fully threaded into the shaft, further rotation will cause the guide plate (40) to rotate, where this guide has shelf (16) having openings (54). The fixation plate (40) is pivotally coupled to the rod of the yoke through the internally threaded shaft (34), which is also a sleeve and rotatably coupled to the guide (18) through the boss (44), and attached to the first guide/plate portion (40) where rotation of the sleeve will cause rotation of the portion (40). The guide plate (18) has slots (78) for an instrument. The rotational paths and location of the apparatus components may become fixed upon termination of the operation of the appropriate assemblies. For the purposes of claim 37 and its dependencies the screws (86) and the slot (66) it interacts with will be considered interacting gears, the threads of the first gear (86) will spin against the wall of slot (66), being an arcuate opening, with will be the interaction of the gear-like portion of the fan-shaped element (40), upon spinning the

screw (86) within the base hole (68) the threads may interact with the slot (86) such that they may affect a slight movement of the plate in on rotation path. The apparatus is designed for use within the angles of the valgus (column 5, lines 7-16). The plate portion (40) is fixed to the bone via the drill bit (56) through one of the holes (54) (column 6, lines 64-68).

FIG-4



***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7-10, 19-22, 31-34, 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pohl (US Pat# 4703751) in view of Helland (US Pat 4488542).

Pohl is explained supra. However Pohl fails to disclose the worm. Helland teaches a worm (15) with a plurality of worm teeth (12') on the wall of the device to mesh with the worm to change the angle of the movable head (13). Figure 10 shows the use of the worm drive about a bone for use in aligning with the bone. It would have been obvious to one of ordinary skill in the art at the time of the inventions to use the worm (15) meshed with the teeth (12') of the device, as taught by Helland with the components of Pohl such that it provides the ability to perform a more precise and uniform adjustment of the angles about a rotational axis such that precision alignment with the bone is possible.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fargie (US Pat # 4736737) –a cutting jig; Duffner (US Pat # 6796986) –osteotomy jig.

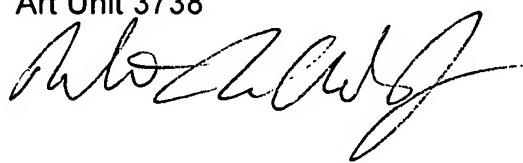
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Amareld, Jr. whose telephone number is 571-272-6170. The examiner can normally be reached on M-F 9am -5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert W Amareld, Jr.  
Examiner  
Art Unit 3738

RWA



BRIAN E. PELLEGRINO  
PRIMARY EXAMINER

